UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PLUMBERS' LOCAL UNION NO. 690 HEALTH PLAN and DELAWARE VALLEY HEALTH CARE COALITION, **Plaintiffs,** **v.** **SANOFI, S.A., et al.,** **Defendants.**	Civ. No. 15-956 (KM) (MAH) **OPINION**

KEVIN MCNULTY, U.S.D.J.

This matter comes before the Court on motions to dismiss the Second Amended Complaint ("2AC", ECF no. 92) for lack of standing under Fed. R. Civ. P. 12(b)(1) and for failure to state a claim upon which relief may be granted under Fed. R. Civ. P. 12(b)(6). Plumbers' Local Union No. 690 Health Plan ("Local 690") and newly-added plaintiff Delaware Valley Health Care Coalition ("DVHCC") bring this action against Sanofi S.A., Sanofi US Services Inc., Sanofi-Aventis U.S., LLC (collectively, "Sanofi"), Fidia Farmaceutici S.p.A. ("Fidia Italy"), Fidia Pharma USA Inc. ("Fidia USA"; together with Fidia Italy, "Fidia"), Accenture PLC(ACN) ("Accenture"), Deloitte LLP, Christopher Viehbacher, Dennis Urbaniak, Raymond Godleski, and Thomas C. Valentine. The plaintiffs claim that they or their members have been caused to pay inflated reimbursements for a Sanofi drug, Hyalgan, as a result of two fraudulent schemes. The first involves the distribution of free samples of Hyalgan, which resulted in artificially high costs; the second involves kickbacks that induced retail pharmacies to switch customers to high cost Sanofi diabetes drugs. I earlier found that the First Amended Complaint ("1AC") failed to allege facts sufficient to link those schemes to any adverse effect on Local

690 or its members. That defect persists, and there are others as well. I will therefore dismiss most of this Second Amended Complaint for lack of standing, and in the alternative for failure to state a claim.

Like the parties, I find Constitutional standing to be a useful lens through which to view the allegations. But particularly where, as here, the standing challenge is a facial one, the distinction between a jurisdictional Rule 12(b)(1) analysis and a Rule 12(b)(6) analysis may blur. Such conundrums need not be solved definitively, because either way the analysis comes out much the same. For example, the lack of a concrete injury for purposes of Rule 12(b)(1) would, *a fortiori,* support a dismissal on 12(b)(6) grounds for failure to allege causation. To assist in review, however, I discuss standing under Rule 12(b)(1) in Section III, *infra,* and then more briefly discuss the same quasi-standing issues under Rule 12(b)(6) in Section IV, *infra.*

I. BACKGROUND

Familiarity with my prior Opinion (ECF No. 89 ("Op.")) and Order (ECF No. 90) dismissing Local 690's 1AC for failure to state a claim is assumed. (ECF No. 89 ("Op.")) Indeed, this opinion must be read in conjunction with the earlier one. Because the First and Second Amended Complaints are in most respects identical, I address here only those facts pertinent to the incremental question presented here: Do the new allegations of the 2AC remedy the deficiencies of the 1AC? I conclude that they do not, and therefore grant these renewed motions to dismiss.

A. Facts

Plaintiff Local 690 is a third-party payor ("TPP") that reimburses its members for the cost of prescription drugs. Its members reside in Pennsylvania, New Jersey, North Carolina, South Carolina, and Florida. (2AC ¶¶ 3, 5) Co-plaintiff DVHCC is a "coalition of union funds who negotiates prescription drug benefit contracts with pharmacy benefit managers ("PBMs") for use by its members." (*Id.* ¶ 6) DVHCC's constituent TPPs, which include

Local 690, are located in the District of Columbia and 12 additional states, including California, Colorado, Delaware, Indiana, Kentucky, Massachusetts, Maryland, Michigan, New York, Ohio, West Virginia, and Wisconsin. (*Id.* ¶ 8)

Sanofi manufactures, markets, and sells prescription pharmaceuticals. (*Id.* ¶¶ 11-20) Fidia owns the rights to Hyalgan, an osteoarthritis drug; until 2011, Fidia licensed the right to sell and market Hyalgan to Sanofi. (*Id.* ¶¶ 21-26) Three of the individual defendants—Viehbacher, Godleski, and Urbaniak—were senior Sanofi officers[1] (collectively, the "Individual Sanofi Defendants," and together with Sanofi, "the Sanofi Defendants"). The fourth individual, Valentine, was a Sanofi sales representative and district sales manager in Orange County, California. (2AC ¶¶ 36-45)

As it did in the 1AC, Local 690, joined now by DVHCC, alleges that Sanofi and Fidia engaged in two fraudulent practices: the "free samples scheme" and the "diabetes drug scheme." The basic mechanics of each have not changed since the 1AC, *see* Op. 5-9, but I provide a brief overview for context.

The gist of the free samples scheme is that Sanofi caused plaintiffs to pay an inflated price for Hyalgan by manipulating federal health care program reimbursement rates from 2005 to 2009.[2] The scheme worked like this: A doctor would purchase Hyalgan direct from Sanofi (or Fidia, after 2011) and administer it to a patient. The doctor then billed a federal health program, such

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1 Or so I gather from the context. The complaint alleges that Godleski and Urbaniak were employed by "Defendants." (2AC ¶¶ 1, 39, 42).

2 Fidia is alleged to have "continued" the scheme after 2011, although virtually all of the 2AC's allegations focus on Sanofi's conduct between 2005 and 2009. (*e.g.*, 2AC ¶¶ 82, 155) As discussed in Part III.B.1., *infra*, there are no factual allegations establishing that Fidia engaged in the same misconduct as Sanofi once it regained Hyalgan's distribution rights.

as Medicare or Medicaid, for reimbursement.[3] (2AC ¶ 94) Medicare reimbursed the doctor in an amount that was based in whole or in part on Hyalgan's average sales price ("ASP");[4] a TPP like Local 690, the patient, or both would pay the difference.[5] (*Id.* ¶¶ 83, 89, 95) From 2005 to 2009, Sanofi allegedly gave doctors free samples of Hyalgan as an incentive to prescribe Hyalgan instead of the drug's lower-cost competitor. (*Id.* ¶ 110, 113) Although Sanofi was required by law to figure those zero-cost samples into Hyalgan's ASP, it didn't; Hyalgan's ASP was therefore artificially high. (*e.g.*, *id.* ¶¶ 85, 87-88, 95, 103) Since Sanofi pegged the price of Hyalgan to its ASP, plaintiffs claim, Medicare and its co-payors paid more for the drug than they should have.[6] (*Id.* ¶¶ 112, 182-83)

The 2AC alleges that the scheme operated nationwide and involved "hundreds of [] thousands" of unreported free samples of Hyalgan. From 2005 through 2009, Sanofi allegedly distributed at least 168,000 unreported samples, each worth in excess of $70. (*Id.* ¶ 115, 161) The 2AC also alleges that Sanofi sales representatives entered into rebate-type arrangements (*e.g.*,

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[3] The 2AC contains a few stray allegations concerning Medicaid and private reimbursement programs. (2AC ¶¶ 91-92, 95, 101, 161) As with the 1AC, however, the 2AC focuses on cost of Hyalgan to plaintiffs vis-à-vis the alleged manipulation of Medicare reimbursement procedures.

[4] The 2AC mentions that average wholesale price ("AWP") was used instead of ASP in some instances, but its particular relevance to the free samples scheme is not clear. (*e.g.*, 2AC ¶¶ 92, 97, 183, 191)

[5] I note that the alleged purpose of the free sample scheme has shifted somewhat since the 1AC. While the 1AC alleges that the free samples scheme was a naked attempt to avoid price competition with Supartz, the lower-cost competitor, the 2AC suggests that the scheme was ultimately an effort to prop up Hyalgan's Medicare reimbursement rate. From 2002 to 2009, Hyalgan shared the same Medicare reimbursement code as Supartz. (2AC ¶ 104, 108) The reimbursement rate for that code was an average of the two drugs' sales prices. (*Id.* ¶ 106-107) Wary of a "downward spiral" in Hyalgan's reimbursement rate, Sanofi (or Fidia, after 2011) buoyed the Hyalgan/Supartz code rate by incentivizing doctors to choose Hyalgan by lowering its "acquisition price" (*i.e.*, effective price) with unreported free samples. (*Id.* ¶ 110)

[6] Plaintiffs specifically allege that they covered a 20% coinsurance obligation for drugs like Hyalgan. (2AC ¶ 89) They also allege that Hyalgan could cost as much as "$1,460, of which Local 690 paid $988.42 and the Local 690 member paid $247.11." (*Id.* ¶ 248)

conditioning the receipt of free samples on the purchase of a certain number of Hyalgan units). These quasi-rebates involved doctors in eight states, including California, New York, Texas, Rhode Island, North Carolina, Indiana, Florida, and Georgia. (*Id.* ¶ 149a-k) No specific example of a Local 690 beneficiary paying an inflated price for Hyalgan is alleged; for the most part, the complaint only avers generally that Local 690 and DVHCC members reimbursed beneficiaries for Hyalgan treatments in 2005 and beyond. (*E.g.* ¶¶ 9, 151-53, 2AC Ex. C)

The second fraudulent practice, the diabetes drug scheme, involved kickback arrangements between Sanofi, Deloitte, and Accenture. The object of the kickback was to induce pharmacies, such as Walgreens and Rite Aid, to switch plaintiffs' beneficiaries from competitors' diabetes drugs to those of Sanofi. From 2012 to 2013, Sanofi, through Viehbacher, Urbianiak, and Godleski, allegedly entered into three such contracts. These contracts were allegedly miscoded in Sanofi's internal project management systems to avoid legal review. (*Id.* ¶ 212, 216-17) In 2014, Diane Ponte, a former Sanofi paralegal, discovered nine such contracts, totaling $34 million, and filed a whistleblower suit in New Jersey state court. (*Id.* ¶¶ 221-22) The 2AC alleges on information and belief that two unnamed Local 690 beneficiaries' diabetes prescriptions were switched in October 2009 and June 2011, resulting in an increased cost to Local 690. (*Id.* ¶¶ 249-250) It is similarly "believed and therefore averred" that DVHCC and its members paid for Sanofi's expensive diabetes drugs as a result of kickback contracts, although no specific instance is identified. (*Id.* ¶ 251)

B. Procedural History

Local 690 filed the original complaint in New Jersey state court on December 18, 2014. On February 6, 2015, defendants removed the case to this Court under the Class Action Fairness Act, 28 U.S.C. 1332(d). (ECF No.1)

where, and how" of the free samples scheme, and "fails to provide the necessary minimal support of its information-and-belief allegations." (Op. 16) Absent from the 1AC was any example of a "doctor's billing or mis-billing anyone (let alone billing Local 690) for a Hyalgan sample (let alone one the doctor received for free)." Also absent was any allegation of "the existence or amount of any [lower] payment that Local 690 would have made but for the alleged free sample scheme." In short, I could not discern from the 1AC "any allegedly unlawful conduct that had any effect on Local 690 and its New Jersey or Pennsylvania beneficiaries." (*Id.* 17)

I found the factual allegations concerning the diabetes drug scheme similarly "skimpy." (*Id.* 21) Stripped of conclusory or speculative allegations, what remained of the 1AC was "a portmanteau allegation that some twelve contracts, contents unknown, broke a number of rules and laws and constituted improper kickbacks to induce Accenture and Deloitte to perform acts that may or may not have occurred, and may or may not have affected Local 690 and its members." (*Id.* 23) For these reasons, among others, I dismissed Local 690's claims under New Jersey's Consumer Fraud Act and Pennsylvania's Unfair Trade Practices and Consumer Protection Law, as well as its claims for disgorgement, unjust enrichment, and conspiracy. The dismissal was without prejudice, however, because "[i]f this misconduct occurred, and if it affected Local 690 and its beneficiaries . . . , it should be possible through reasonable investigation to uncover specific facts and examples of it." (*Id.* 3)

On July 11, 2016, Local 690 filed the 2AC. For the most part, its allegations are cut-and-pasted from the 1AC. There are a few stylistic and structural innovations, however. Some allegations are dropped: The 2AC abandons all claims against the Genzyme Corporation, and it also drops the disgorgement claim against all defendants. On the other hand, the 2AC adds DVHCC as a plaintiff, and adds claims under three more states' consumer protection and unfair practice statutes. The 2AC also now includes allegations in which plaintiffs disclaim knowledge of what they formerly alleged as true,

stating for example that "only Sanofi knows the specifics of its sampling conduct" and "only discovery will reveal such specifics to Plaintiffs." (*E.g.*, 2AC ¶¶ 154-56)

On September 12, 2016, defendants filed these renewed motions to dismiss the 2AC. (ECF Nos. 104, 105, 106, 107, 108) Accenture and the Sanofi Defendants move to dismiss for lack of standing and failure to state a claim. Deloitte and Fidia move to dismiss for failure to state a claim. Valentine moves to dismiss for lack of personal jurisdiction and failure to state a claim.

C. Claims

The alleged free samples scheme involves defendants Sanofi, Fidia, and Valentine. The alleged diabetes drug scheme involves Deloitte, Accenture, and the Sanofi Defendants (*i.e.*, Sanofi plus Viehbacher, Urbaniak, and Godleski). The following claims, asserted against all defendants and encompassing both schemes, are common to the 1AC and 2AC:

1) violations of New Jersey's Consumer Fraud Act ("NJCFA"), N.J. Stat. Ann. § 56:8-1, et seq;
2) violations of Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTPCPL"), 73 P.3. § 201-1, et seq;[7]
3) unjust enrichment; and
4) conspiracy, concert of action, or aiding or abetting.

To these, the 2AC adds four claims:

1) violations of New York's General Business Law ("NYGBL"), § 349, et seq;

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[7] The following provisions are specifically cited: §§ 201-2(4)(ii) (causing confusion of the source of a good or service); 201-2(4)(v) making representations about a good or service); 201-2(4)(ix) (advertising a good or service with the intent not to sell them as advertised); 201-2(4)(xi) (misrepresenting reasons for price reductions); 201-2(4)(xii) (offering to pay a buyer for a contract for goods or services when such compensation is contingent on the occurrence of a subsequent event); and 201-2(4)(xxi) (any other deceptive conduct—a catchall).

2) violations of California's Unfair Competition Law Business & Professions Code ("CUCL"), § 17200, et seq;

3) violations of California's Consumer Legal Remedies Act ("CLRA"), California Civil Code §§ 1750, et seq; [8] and

4) violations of Maryland's Consumer Protection Act ("MCPA"), §§ 13-101, et seq.[9]

The 2AC requests damages and unspecified injunctive relief.

II. STANDARDS

A. Rule 12(b)(1) Motion to Dismiss

Section III of this Opinion analyzes the motions insofar as they seek to dismiss the complaint for lack of standing under Fed. R. Civ. P. 12(b)(1). A Rule 12(b)(1) motion, because it implicates the Court's subject matter jurisdiction, may be raised at any time. *Iowana v. Ford Motor Co.*, 67 F. Supp. 2d 424, 437-38 (D.N.J. 1999). Rule 12(b)(1) challenges may be either facial or factual attacks. *See* 2 Moore's Federal Practice § 12.30[4] (3d ed. 2007); *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977).

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8 These provisions are specifically cited: §§ 1770(a)(2) (misrepresenting source, sponsorship, approval, or certification of goods and services); 1770(a)(3) (misrepresenting the affiliation, connection, or association with, or certification by, another); 1770(a)(4) (using deceptive representations or designations of geographic origin in connection with goods or services); 1770(a)(5) (representing that goods have characteristics, ingredients, uses, benefits, or quantities that they do not have); and 1770(a)(8) (disparaging the goods, services, or businesses of another by a false or misleading act of another).

9 These provisions of Maryland's Consumer Protection Act are cited: §§ 13-301(1) (misrepresentation that deceived customers); 13-301(2) (representing that consumer goods or services have a characteristic, ingredient, use, benefit, or quantity that they do not have); 13-301(3) (omitting a material fact that deceives or tends to deceive); 13-301(4) (disparaging goods or services of another by misrepresentation of a material fact); 13-301(6) (misrepresenting the existence or amount of a price reduction); 13-301(8) (stating falsely the reason for offering or supplying consumer goods or services a sale or discount prices); 13-301(9) (deceiving or misrepresenting or omitting any material fact with the intent that a consumer rely on the same in connection with the sale of any consumer goods).

A facial Rule 12(b)(1) asserts that the allegations of the complaint do not set forth sufficient grounds to establish subject matter jurisdiction. *Iwanowa*, 67 F. Supp. 2d at 438. "In reviewing a facial attack, the court must only consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff." *Lincoln Ben. Life Co. v. AEI Life, LLC*, 800 F.3d 99, 105 (3d Cir. 2015) (citing *Gould Elecs. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000)). A facial Rule 12(b)(1) motion assumes that the allegations of the complaint are true. *Cardio–Med. Assoc., Ltd. v. Crozer–Chester Med. Ctr.*, 721 F.2d 68, 75 (3d Cir. 1983); *Iwanowa*, 67 F. Supp. 2d at 438. "With respect to 12(b)(1) motions in particular, '[t]he plaintiff must assert facts that affirmatively and plausibly suggest that the pleader has the right he claims (here, the right to jurisdiction), rather than facts that are merely consistent with such a right.'" *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 244 (3d Cir. 2012) (quoting *Stalley v. Catholic Health Initiatives*, 509 F.3d 517, 521 (8th Cir. 2007)). *See also Lincoln Ben. Life Co.* 800 F.3d at 105 (further discussing distinctions between facial and factual attack).

B. Rule 12(b)(6) Motion to Dismiss

Section IV of this Opinion analyzes the motions insofar as they seek to dismiss the complaint under Federal Rule of Civil Procedure 12(b)(6). Rule 12(b)(6) provides for the dismissal of a complaint, in whole or in part, if it fails to state a claim upon which relief can be granted. The moving party, ordinarily the defendant, bears the burden of showing that no claim has been stated. *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005). For purposes of a motion to dismiss, the well-pleaded factual allegations of the complaint must be taken as true, with all reasonable inferences drawn in plaintiff's favor. *Phillips v. County of Allegheny*, 515 F.3d 224, 231 (3d Cir. 2008) ("reasonable inferences" principle not undermined by

Federal Rule of Civil Procedure 8(a) does not require that a complaint contain detailed factual allegations. Nevertheless, "a plaintiff's obligation to

provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The factual allegations must be thus sufficient to raise a plaintiff's right to relief above a speculative level. The claim, in other words, must be "plausible on its face." *See id.* at 570; *see also Umland v. PLANCO Fin. Servs., Inc.*, 542 F.3d 59, 64 (3d Cir. 2008). A claim has "facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). While "[t]he plausibility standard is not akin to a 'probability requirement' . . . it asks for more than a sheer possibility." *Iqbal*, 556 U.S. at 678. All of this has been distilled by the Third Circuit in a three-step process:

> To determine whether a complaint meets the pleading standard, our analysis unfolds in three steps. First, we outline the elements a plaintiff must plead to a state a claim for relief. *See* [*Iqbal*, 556 U.S.] at 675; *Argueta* [*v. U.S. Immigration & Customs Enforcement*, 643 F.3d 60, 73 (3d Cir. 2011)]. Next, we peel away those allegations that are no more than conclusions and thus not entitled to the assumption of truth. *See Iqbal*, 556 U.S. at 679; *Argueta*, 643 F.3d at 73. Finally, we look for well-pled factual allegations, assume their veracity, and then "determine whether they plausibly give rise to an entitlement to relief." *Iqbal*, 556 U.S. at 679; *Argueta*, 643 F.3d at 73. This last step is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679.

Bistrian v. Levi, 696 F.3d 352, 365 (3d Cir. 2012). *Accord Carpenters Health and Welfare Fund of Philadelphia v. Management Resource Systems, Inc.*, 837 F.3d 378, 382 (3d Cir. 2016) (citing *Bistrian*).

C. Rule 9(b)

To analyze the Rule 12(b)(6) motion, I must determine whether the ordinary Rule 8(a) or the more stringent Rule 9(b) pleading standard applies to plaintiffs' state law consumer protection and unfair practice claims. With the exception of the NYGBL claim, I resolve this issue as I did in my prior Opinion: I will apply Rule 9(b) "[t]o the extent the scheme rests on falsehoods or misrepresentations—*e.g.*, about the true price of the drugs, about the nature of the contracts, or the *bona fides* of the pharmacies' prescription practices;" contrariwise, I will apply Rule 8(a) "[t]o the extent the claims may be viewed in the alternative as alleging, *e.g.*, regulatory violations or unconscionable business practices." (Op. 14)

For claims of fraud, Federal Rule of Civil Procedure 9(b) imposes a heightened pleading requirement, over and above that of Rule 8(a). Specifically, it requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "Malice, intent, knowledge, and other conditions of a person's mind," however, "may be alleged generally." *Id.* That heightened pleading standard requires the plaintiff to "state the circumstances of the alleged fraud with sufficient particularity to place the defendant on notice of the precise misconduct with which it is charged." *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007) (internal quotation and citation omitted).

In general, "[t]o satisfy this heightened standard, the plaintiff must plead or allege the date, time, and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation." *Id.* "Plaintiff must also allege who made the misrepresentation to whom and the general content of the misrepresentation." *Lum v. Bank of Am.*, 361 F.3d 217, 224 (3d Cir. 2004) (internal citation omitted); *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276–77 (3d Cir. 2006) ("Rule 9(b) requires, at a minimum, that plaintiffs support their allegations of fraud with all of the essential factual background that would accompany the first paragraph of any

newspaper story—that is, the who, what, when, where and how of the events at issue.") (internal quotation and citation omitted)).

While the plaintiff must provide allegations sufficient to provide defendants "notice of the 'precise misconduct' with which defendants are charged," Rule 9(b) does not "require plaintiffs to plead issues that may have been concealed by the defendants." *Rolo v. City Investing Co. Liquidating Trust*, 155 F.3d 644, 658 (3d Cir. 1998) (quoting *Seville Indus. Machinery v. Southmost Machinery*, 742 F.2d 786, 791 (3d Cir. 1984) and citing *Christidis v. First Pennsylvania Mortg. Trust*, 717 F.2d 96, 99 (3d Cir. 1983)). The particularity requirement, for example, can be relaxed in cases of corporate fraud because plaintiffs cannot be expected to have personal knowledge of the details of corporate internal affairs. *Craftmatic Sec. Litig. v. Kraftsow*, 890 F.2d 628, 645 (3d Cir. 1989). Even so, a plaintiff must still allege that facts based on information and belief are in the exclusive control of a defendant and "must accompany such an allegation with a statement of facts upon which their allegation is based." *Shapiro v. UJB Fin. Corp.*, 946 F.2d 272, 285 (3d Cir. 1992); *see also Zavala v. Wal-Mart Stores, Inc.* 393 F. Supp. 2d 295, 314 (D.N.J. 2005), *aff'd sub nom. Zavala v. Wal-Mart Stores, Inc.*, 691 F.3d 257 (3d Cir. 2012). In other words:

> A complaint must delineate at least the nature and scope of plaintiffs' effort to obtain, before filing the complaint, the information needed to plead with particularity. This requirement is intended to ensure that plaintiffs thoroughly investigate all possible sources of information, including but not limited to all publicly available relevant information, before filing a complaint.

Shaprio, 964F.2d at 285.

The state consumer protection and unfair practice statutes under which plaintiffs sue encompass fraud, but also a range of other unconscionable

or deceptive business practices. As this issue relates to the NJCFA[10] and UTPCPL,[11] I have already ruled: Rule 9(b) applies to the extent each such claim "rests on falsehood or misrepresentations"; Rule 8(a) applies to the extent it rests on "regulatory violations or unconscionable business practices." (Op. 14) (citing *Smajlaj*, 782 F. Supp. at 98 n.9; *Belmont*, 708 F.3d at 498 n.33)) Plaintiffs offer no reason to adopt any different approach with respect to the MCPA,[12] CUCL, and CLRA claims.[13] "I will therefore, in the course of the analysis, advert to both" the Rule 8 and 9 standards. (Op. 14)

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10 To state a prima facie case under the NJFCA a plaintiff must allege three elements: "(1) unlawful conduct by defendant; (2) and ascertainable loss by the plaintiff; and (3) a causal connection between the defendant's unlawful conduct and the plaintiff's ascertainable loss." *Bosland v. Warnock Dodge, Inc.*, 964 A.2d 741, 749 (N.J. 2009). "Some claims under the [NJ]CFA may not require pleadings complying with Rule 9(b). Not every such claim involves an affirmative misrepresentation or material omission." *Smajlaj v. Campbell Soup Co.*, 782 F. Supp. 2d 84, 98 n.9 (D.N.J. 2011) (alteration added).

11 "To bring a private cause of action under the UTPCPL, a plaintiff must show that he justifiably relied on the defendant's wrongful conduct or representation and that he suffered harm as a result of that reliance." *Yocca v. Pittsburgh Steelers Sports, Inc.*, 578 Pa. 479, 501 (2004). Rule 9(b) does not apply to the extent that the alleged conduct is not based on fraudulent conduct. *Belmont v. M.B. Partners, Inc.*, 708 F.3d 470, 498 n.33 (3d Cir. 2013).

12 To bring an action under the MCPA, a plaintiff must allege "(1) an unfair or deceptive practice or misrepresentation that (2) is relied upon, and (3) causes [him] actual injury." *Farasat v. Wells Fargo Bank, N.A.*, 913 F. Supp. 2d 197, 205 (D. Md. 2012) (quoting *Stewart v. Bierman*, 859 F. Supp. 2d 754, 768 (D. Md. 2012) (citing *Lloyd v. Gen. Motors Corp.*, 397 Md. 108, 916 A.2d 257, 277 (Md. 2007)) (alteration in original)). "MCPA claims that sound in fraud are subject to the heightened pleading standards of Federal Rule of Civil Procedure 9(b)." *Spaulding v. Wells Fargo Bank, N.A.*, 920 F. Supp. 2d 614, 623 (D. Md. 2012).

13 The CUCL prohibits acts or practices that are, (1) unlawful; (2) fraudulent; or (3) unfair. Cal. Bus. & Prof. Code § 17200. Each prong of the UCL constitutes a separate and distinct theory of liability. *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009). *Cel-Tech Communications, Inc. v. L.A. Cellular Tel. Co.*, 20 Cal. 4th 163, 180, (1999). The UCL proscribes "unfair competition," which includes "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising." § 17200. The fraudulent practice prong of the UCL "has been understood to be distinct from common law fraud." *In re Tobacco II Cases*, 46 Cal. 4th 298, 312, 93 Cal. Rptr. 3d 559, 207 P.3d 20, 29 (Cal. 2009). "'A [common law] fraudulent deception must be actually false, known to be false by the perpetrator and reasonably relied upon by a victim who incurs damages. None of these elements are required to state a claim . . . under the UCL." *Id.* Claims under fraudulent prong still require a

I will, however, apply the ordinary pleading standard to plaintiffs' NYGBL claims. "Section 349 [of the NYGBL] extends 'well beyond common law fraud to cover a broad range of deceptive practices,' and as such, claims under § 349 are not subject to the heightened pleading standard of Fed. R. Civ. P. 9(b)." *Argabright v. Rheem Mgf. Co.*, 201 F. Supp. 3d 578, 607 (D.N.J. 2016) (quoting *Pelman ex rel. Pelman v. McDonald's Corp.*, 396 F.3d 508, 511 (2d Cir. 2005)); *see also City of New York v. Smokes-Spirits.com, Inc.*, 541 F.3d 425, 455 (2d Cir. 2008) ("[A]n action under § 349 is not subject to the pleading-with-particularity requirements of Rule 9(b), Fed. R. Civ. P., but need only meet the bare-bones notice-pleading requirements of Rule 8(a).") (quoting *Pelman*, 396 F.3d at 511).[14] Defendants concede that Rule 8 should apply to plaintiffs' NYBGL claims. For those claims only, then, I will apply the ordinary notice-pleading standard.

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plaintiff to plead that the alleged misrepresentation was directly related to the injurious conduct and that the plaintiff actually relied on the alleged misrepresentation. *Id.*

The CLRA is similarly broad: It prohibits "unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or which results in the sale or lease of goods or services to any consumer." Cal. Civ. Code § 1770(a). Conduct that is "likely to mislead a reasonable consumer" violates the CLRA. *Colgan v. Leatherman Tool Grp., Inc.*, 135 Cal. App. 4th 663, 680 (2006) (quoting *Nagel v. Twin Labs., Inc.*, 109 Cal. App. 4th 39, 54 (2003)).

Under either statute, "only allegations ('averments') of fraudulent conduct must satisfy the heightened pleading requirements of Rule 9(b)," if fraud is not an essential element of the claim. *Vess Ciba-Geigy Corp. USA*, 317 F.3d. 1097, 1105 (9th Cir. 2003); *Kearns*, F.3d at 1126-27.

[14] "A plaintiff under section 349 must prove three elements: first, that the challenged act or practice was consumer-oriented; second, that it was misleading in a material way; and third, that the plaintiff suffered an injury as a result of the deceptive act." *Stutman v. Chemical Bank*, 95 N.Y.2d 24, 29 (2000).

III. ANALYSIS: RULE 12(B)(1)

The motions seek, in part, to dismiss the 2AC under Rule 12(b)(1). Jurisdiction is lacking, they say, because the 2AC fails to allege that the plaintiffs have suffered a compensable, concrete injury that is attributable to defendants' conduct. In terms of alleging concrete injury, the 2AC fails to improve upon the 1AC in any way that matters; plaintiffs still fail to allege crucial specifics about the free samples or diabetes drug schemes. While the 2AC contains many general statements about defendants' misconduct, there are virtually no allegations that tie such alleged misconduct to any harm suffered by Local 690 or DVHCC.

A. Legal Standard

Defendants advance a number of constitutional and statutory standing arguments. Plaintiffs, defendants say, failed to plead any injury or causation, and therefore lack first-party standing (or, in DVHCC's case, associational standing), to bring these claims. I mostly agree. Local 690 has failed to allege any facts suggesting that it suffered an actual injury traceable to either scheme. And DVHCC, which is made up of TPPs including Local 690, lacks standing to bring damages claims on behalf of others, with one exception: it does have standing to seek prospective injunctive relief on behalf of its New York and California members, but only against Fidia.

A plaintiff must establish standing to sue under Article III of the United States Constitution, which limits the jurisdiction of federal courts to "Cases" and "Controversies." To meet the "irreducible constitutional minimum" of Article III, the plaintiff must establish three elements:

> First, the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the

> independent action of some third party not before the court. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Schering-Plough, 678 F. 3d at 244 (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)).

A named plaintiff in a putative class action must possess standing, just like that of any other plaintiff. *See, e.g., Lewis v. Casey*, 518 U.S. 343, 357 (1996) ("That a suit may be a class action . . . adds noting to the question of standing, for even named plaintiffs who represent a class 'must allege and show that they have been personally injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent.'") (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 40 n. 20 (1977)). "[I]f none of the named plaintiffs purporting to represent a class establishes the requisite case or controversy with the defendants, none may seek relief on behalf of himself or any other member of the class." *O'Shea v. Littleton*, 414 U.S. 488, 494 (1974).

Standing is typically analyzed claim by claim. *See, e.g.*, 678 F.3d at 245 ("Since 'standing is not dispensed in gross,' a plaintiff who raises multiple causes of action 'must demonstrate standing for each claim he seeks to press.'") (quoting *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006) (internal citations omitted)). Each count of the 2AC, however, is predicated on the same allegedly deceptive or fraudulent course of conduct; the free samples scheme and the diabetes drug scheme are the twin threads that run through all of the legal claims. Instead of analyzing the 2AC count by count, then, I analyze it scheme by scheme.

1. Free Samples Scheme

i. Local 690

Local 690 alleges on behalf of its beneficiaries in New Jersey, Pennsylvania, North Carolina, South Carolina, and Florida, that it paid an inflated price for Hyalgan because the drug's ASP did not take into account free

samples provided to doctors across the country. Here, as in the 1AC, the "dollars, dates, or circumstances" of any particular overcharge are not identified. (Op. 17) The 2AC instead avers generally that "Local 690 has reimbursed for Hyalgan during the relevant time period." (2AC ¶ 9) But those allegations, taken as true, do not establish anything "more than a sheer possibility" that Local 690 suffered an injury-in-fact caused by the defendants' conduct. *See Schering-Plough*, 678 F.3d at 243-44 (quoting *Iqbal*, 556 U.S. at 678)). More is required to establish that Local 690 is plausibly—not merely conceivably—a victim of the free samples scheme.

I look for that something more in the allegations new to the 2AC. The 2AC contains two new groups of allegations that bear on the issue of standing:

> (1) A settlement that resolved allegations involving free samples in New Jersey, California, Maryland, and New York (the Giddarie Settlement"); and
>
> (2) Examples of Sanofi sales representatives misusing Hyalgan samples in California, New York, Texas, Rhode Island, North Carolina, Indiana, Florida, and Georgia (as relevant here, the "Florida and N.C. Sales Rep Conduct").

These two groups of allegations overlap with Local 690's territory as to the states of New Jersey, North Carolina, and Florida; the other states I set aside.

The Giddarie Settlement is potentially relevant insofar as it involves New Jersey and North Carolina. Sanofi, Local 690 says, "agreed to pay New Jersey" an unidentified portion of a $617,000 global settlement "to account for the value of its Hyalgan samples disseminated in the state" between 2005 and 2009.[15] (2AC ¶ 154) Elsewhere, the 2AC alleges that Sanofi paid North Carolina got $41,713.36 in restitution, interest, and other costs out of that $617,000

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[15] I read somewhat between the lines here. The Giddarie complaint alleged a time period between 2005 and 2009. The Giddarie Settlement itself does not appear to be publicly available, and its time frame may be different.

pot. (*Id.* ¶ 197)[16] But there is no non-speculative factual allegation that Local 690 actually paid an inflated price for Hyalgan attributable to any free sample distributed in New Jersey or North Carolina. The Giddarie Settlement therefore adds very little to the analysis.

Here is what I mean. Assume that some quantity of free Hyalgan samples was distributed in each state. But to which doctors? And for the treatment of which patients? Without any pertinent facts or examples, the most that can be inferred from the fact that Sanofi settled the Giddarie for general misconduct in New Jersey or North Carolina is that these practices may or may not have affected Local 690's beneficiaries in those states.[17] To look at it another way, any concrete connection to the plaintiff is lacking; there is no minimal factual allegation that Local 690 ever paid for a Hyalgan treatment administered to one of its New Jersey or North Carolina beneficiaries *at all.* Thus the Giddarie settlement does not plausibly suggest that Local 690 has suffered any injury-in-fact traceable to defendants' conduct in New Jersey.

That leaves the second group of allegations, the Florida and N.C. Sales Rep Conduct. Florida and North Carolina are states in which Local 690's beneficiaries are located. The 2AC alleges, albeit on information and belief, that a "South Florida based sales representative of Sanofi . . . promised 15 Hyalgan samples . . . for every 50 Hyalgan units" purchased by an unnamed medical practice, and that the sales representative "delivered over 200 Hyalgan samples" to that practice in 2007 and 2008. (2AC ¶ 149j) Something similar allegedly occurred in North Carolina in 2008 and 2009: a sales representative allegedly promised an unnamed medical practice "25 free Hyalgan units . . . for every 100 units purchased," and "over 200 Hyalgan samples were delivered" to that practice. (2AC ¶ 149h) These allegations creep closer to establishing that

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16 The Department of Justice allegedly took $26,902.72 of North Carolina's share of the award. (2AC ¶ 197).

17 Local 690 indeed candidly admits that "only Sanofi knows the specifics of its sampling conduct within New Jersey," and it does not know "which doctors in which states received free samples and billed for free samples of Hyalgan." (2AC ¶¶ 124, 154)

Local 690 suffered an injury as a result of defendant's conduct, but they too fail to bridge the gap between conceivability and plausibility.

To illustrate the point, accept, as before, the truth of these allegations (although they are made on information and belief, and their basis is not disclosed). Assume that Sanofi sales representatives entered into rebate-type agreements with at least two doctors in North Carolina and Florida, and assume further, though less plausibly, that this practice drove up the ASP of Hyalgan in those two states. There is still no allegation that *Local 690 or its beneficiaries* paid, let alone overpaid, anything for Hyalgan in those states during the relevant period. The relevant physicians' patients may or may not have been Local 690 beneficiaries; if so, those beneficiaries may or may not have been prescribed Hyalgan. I am of course mindful that "[t]he plausibility standard is not akin to a 'probability requirement.'" *Iqbal*, 556 U.S. at 678; *see also In re Schering Plough*, 678 F.3d at 244 (the plaintiff must "plausibly suggest that the pleader has the right he claims (here, the right to jurisdiction), rather than facts that are merely consistent with such a right.'") But the 2AC contains no factual allegation suggesting on any basis that any Local 690 beneficiary was billed for any Hyalgan treatment in North Carolina or Florida in 2007, 2008, or 2009. In short, maybe someone is alleged to have been overbilled in those states during those years, but there is no allegation that that someone is Local 690.

As to North Carolina and Florida, the 2AC falls back on a broad generalization: "[P]lan beneficiaries," Local 690 alleges, were treated "with Subject Drugs [by the North Carolina and Florida medical providers] and thereafter sought and received reimbursement for Subject Drugs from Plaintiffs at [] inflated prices." (2AC ¶ 53) This allegation is simply too general and conclusory. Local 690, despite one opportunity to amend, has still failed to allege any fact that connects practices by Sanofi personnel even one instance in which Local 690 paid an inflated price for Hyalgan. And even assuming that

this allegation passes the minimum constitutional standing threshold, it is not sufficient to state a claim under Rule 12(b)(6). *See* Part IV.A., *infra.*

Local 690 attempts to evade this fundamental pleading deficiency by pointing the finger at Sanofi and Fidia. Those defendants, Local 690 alleges, were required by law to track their samples, but they didn't. That is why Local 690 cannot now demonstrate that any specific doctor billed or mis-billed a Local 690 beneficiary for Hyalgan.[18] But there is no reason that Local 690 should thereby be excused from holding up its end of the jurisdictional inquiry: surely Local 690 could ascertain from its own information or records which of *its own beneficiaries* it reimbursed for Hyalgan.[19] Indeed, it is likely that *only* Local 690, and not Sanofi, would have the information that could conceivably connect any wrongdoing by Sanofi to any injury suffered by Local 690. Because Local 690 has not alleged factually that it paid for a Hyalgan treatment in North Carolina or Florida at all, it necessarily has not alleged that it overpaid, and therefore it has not alleged that it suffered an injury-in-fact.

ii. DVHCC

DVHCC, too, seeks to bring claims based on the free samples scheme. DVHCC is not itself a TPP but rather an association of TPPs; it argues that it has standing based on injuries to its members.

By its own admission, DVHCC does not have first-party standing. The 2AC explicitly alleges that DVHCC's member TPPs, not DVHCC, reimbursed beneficiaries for Hyalgan. (2AC ¶ 10) DVHCC, in short, never paid anything for Hyalgan at any time; it therefore does not assert an injury suffered by itself.

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[18] At the same time, plaintiffs aver that defendants *do* have such information within their exclusive control, and that this is a reason to deny defendants' motion to dismiss and allow this case to proceed towards discovery.

[19] I note that DVHCC apparently conducted such an investigation, and has submitted a chart demonstrating that its member plans made thousands of dollars in payments for Hyalgan from 2005 to 2014 in New Jersey, California, Maryland, and New York. (2AC Ex. C) There are other problems, however, with DVHCC's standing. *See infra.*

The real dispute here is about associational standing. Associational standing requires that (1) the organization's "members . . . have standing to sue on their own; (2) the interests the organization seeks to protect are germane to its purpose; and (3) neither the claim asserted nor the relief requires individual participation by its members." *NAAMJP v. Simandle*, 2015 U.S. Dist. LEXIS 115865, at *11 (D.N.J. Sept. 1, 2015) (quoting *Blunt v. Lower Merion School Dist.*, 767 F.3d 247, 279 (3d Cir. 2014)), *aff'd*, 658 F. App'x 127 (3d. Cir. 2017)). The first two prongs are grounded in the constitution; the third is prudential. *United Food & Commer. Workers Union Local 751 v. Brown Group*, 517 U.S. 544, 556-558 (1997). Because there is no dispute that the interests DVHCC seeks to protect are germane to its purpose, I address here only the first and third prongs. I find that DVHCC may bring claims on behalf of some of its members, but only for injunctive relief, and only against Fidia.

a. The standing of DVHCC's members

The first prong of the associational standing test—the Constitutional requirement that DVHCC's members themselves possess standing—dooms many of DVHCC's claims.

DVHCC sues on behalf of its TPP members in over a dozen states.[20] The 2AC, however, alleges only that DVHCC's members in New Jersey, Maryland, New York, and California paid for Hyalgan treatments between 2005 and 2014. Standing for the vast majority of these members is based on the double-barreled allegation that (a) Hyalgan samples were distributed in these states and (b) some DVHCC members reimbursed for some Hyalgan treatments in some of those same states in the same time period. (2AC ¶¶ 9-10) This allegation, as noted above, is general and conclusory; it requires a closer look in order to rise above the conjectural level.

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[20] They are: Pennsylvania, New Jersey, California, Colorado, Delaware, Indiana, Kentucky, Massachusetts, Maryland, Michigan, North Carolina, New York, Ohio, South Carolina, West Virginia, and Wisconsin. DVHCC also claims to have members in Washington, D.C.

Peeling away the layers of generic allegations contained in the 2AC, *see Bistrian, supra,* I find that there are two states—New York and California—where DVHCC presents a plausible case for its members' standing. In those states, the 2AC alleges, (1) DVHCC's members paid for Hyalgan while free samples of the drug were simultaneously being distributed to doctors who treated DVHCC's members' beneficiaries; (2) a Sanofi sales representative entered into a specific rebate-type arrangement with a medical practice which treated DVHCC's members' beneficiaries; and (3) Sanofi settled the Giddarie matter for some amount of money to account for the free samples distributed in that state. (2AC Ex. C, ¶¶ 149a-e, 156-57, 159-60)[21] That case, of course, is far from airtight; there is still no factual allegation that connects these fairly high-level allegations to a specific instance in which a DVHCC member paid an inflated price for Hyalgan.[22] Nevertheless, we are at the pleading stage, and DVHCC has articulated a theory that gives its claims a hue of plausibility. DVHCC says that defendants' manipulation of reimbursement procedures resulted in across-the-board inflation of the price of Hyalgan to Medicare and

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[21] As to New Jersey and Maryland, the 2AC does contain allegations (1) and (3), and the 2AC does specifically allege that "Sanofi agreed to pay Maryland the sum of $5,026.35 out of the $617,000 paid" to resolve all claims as to all states. (2AC ¶ 158) Still, there is no factual allegation that an illegal sampling arrangement transpired in Maryland or New Jersey, let alone one that affected DVHCC members. And even if DVHCC did have standing to pursue claims on behalf of its Maryland members, I would still dismiss it for failure to state a claim. *See* Part III.B-D.

[22] That type of allegation will ultimately prove to be critical to making sense out of the allegations in the 2AC. Take one representative example. Quoting an email, the 2AC alleges that a Sanofi sales representative promised Southern California-based Physician Practice A that "orders @ 93 you get 25 samples. Orders at $77 you get 15." (2AC ¶ 149a) This is the most specific allegation of rebate-type arrangement between a Sanofi sales representative and a doctor, but there is no allegation to anchor it to a specific date or time. While it is alleged upon information and belief that the agreement occurred sometime in the four years between 2005 and 2009, Plan B, the sole DVHCC member that allegedly paid a specific amount for Hyalgan, is located in Northern California, and only made such payments from 2007 to 2012. (*Id.* ¶ 156, 2AC Ex. C) Furthermore, there is no allegation that Plan B actually reimbursed for Hyalgan administered by Physician Practice A. Logical gaps of this kind plague the 2AC.

its co-payors.[23] It follows that if DVHCC's members reimbursed for Hyalgan during the period of price inflation, then they may have suffered an injury that could be proven. So taking all allegations as true and construing all inferences in favor of DVHCC, it is plausibly alleged that DVHCC's members suffered an injury-in-fact traceable to defendants' misuse of free Hyalgan samples in New York and California.

b. The individual-participation prong

The third, "no-individual-participation" prong of the associational standing analysis, however, is devastating to whatever claims might survive the prong one analysis. Indeed, it eliminates all of DVHCC's damages claims, as well as its injunctive claims against all but one defendant.

The crux of this lawsuit is that DVHCC's members allegedly paid more for Hyalgan than they should have. Naturally, DVHCC seeks money damages on their behalf to make them whole. But "[b]ecause claims for monetary relief usually require individual participation, courts have held associations cannot generally raise these claims on behalf of their members." *Pa. Psychiatric Soc'y Green Spring Health Servs.*, 280 F.3d 278, 284-285 (3d Cir. 2002); *see also United Food*, 517 U.S. at 554-558; *Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 342-344 (1977); *Conn State Dental Ass'n v. Anthem Health Plans, Inc.*, 591 F.3d 1337, 1354 (11th Cir. 2009) ("Damage claims are incompatible with associational standing because such claims usually require 'individualized proof.'") (quoting *Warth v. Seldin*, 422 U.S. 490, 515-16 (1975)); *Bano v. Union Carbide Corp.*, 361 F.3d 696, 714 (2d Cir. 2004) ("We know of no Supreme Court or federal court of appeals ruling that an association has standing to pursue damages on behalf of its members.")

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[23] This may be viewed as some sort of Medicare analogy to the fraud-on the-market theory, which is unique to securities law. Such a theory, as applied here, is rife with difficulties. It presumes, for example, an efficient market in which the participants possess all material information, so that misinformation may be presumed to affect every individual purchaser in the relevant period.

This third prong, as DVHCC points out, is a prudential one. But "[t]o see *Hunt's* third prong as resting on less than constitutional necessity is not, of course, to rob it of its value." *United Food*, 517 U.S. at 556. And its value is amply demonstrated in a case where the complaint fails to suggest that the plaintiff will be able to show damages with any particularity. *Id.* ("[The bar against damages in associational standing cases] may guard against the hazard of litigating a case to the damages stage only to find the plaintiff lacking detailed records or the evidence necessary to show the harm with sufficient specificity.") In short, I see no reason to depart from the usual rule here.[24] The damages claims should be dismissed on prong three grounds.

Prong three does not bar DVHCC from seeking injunctive and declaratory relief on behalf of its members. Such relief, by definition, is prospective. *See, e.g., Los Angeles v. City of Lyons*, 461 U.S. 95, 103 (1983) ("[P]ast exposure to illegal conduct does not in itself show a present case or controversy regarding injunctive relief . . . if unaccompanied by continuing, present, adverse effects."); *Corliss v. O'Brien*, 200 Fed. App'x. 80, 84 (3d Cir.

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[24] In the papers, DVHCC denies that there is any need for individualized proof of damages, and therefore argues that the purpose animating the rule—*i.e.*, the need for individual participation on the part of DVHCC's members—is inapplicable here:

> [B]ecause the DVHCC acts as a group purchasing organization who negotiates template agreements with pharmacy benefits managers for its members - who are themselves putative class members - there is no need for individualized proof of damages because damages are the same for all the members when reimbursed under the agreements negotiated by the DVHCC. Because its members apply the same reimbursement formula, as negotiated by DVHCC, there exists common basis for calculating individual class claims and proving damages.

(ECF No. 122, p. 29) Of course, statements in briefs cannot serve to amend a deficient complaint. But at any rate, this explanation only poses more questions: What template agreements? Which DVHCC members adopted those agreements? And when and where did reimbursements for Hyalgan pursuant to those agreements occur, and to whom, and in what amount? The problem remains that no TPP has stepped up to allege that it reimbursed for Hyalgan at some relevant time and place, and overpaid as a result. These questions only underscore the need for individual participation from DVHCC's members on the question of damages.

2006) ("Declaratory judgment is inappropriate solely to adjudicate past conduct.") (citing *Gruntal & Co., Inc. v. Steinberg*, 837 F. Supp. 85, 89 (D.N.J. 1993)).

No such prospective relief can be granted as to Sanofi, which has not marketed or sold Hyalgan since 2011, or Valentine, who has been barred from participating in federal health care programs since June 2013. (2AC ¶¶ 23, 258, 261) To the extent that DVHCC has standing to seek injunctive or declaratory relief, then, it may do so only against Fidia, which allegedly assumed the rights to market and sell Hyalgan in the United States in 2011.

In sum, Local 690 does not have standing to bring any claims related to the free samples scheme. DVHCC does, but only on behalf of its New York and California beneficiaries, and only for injunctive relief against Fidia.

2. Diabetes Drug Scheme

As to the diabetes drug scheme, I analyze Local 690 and DVHCC's standing claims together. The 2AC fails to allege any facts that would demonstrate injury or causation as to either plaintiff. The 2AC cites to no example of DVHCC or its members having paid an increased cost for a Sanofi diabetes drug due to a pharmacy's "switching" a beneficiary from a lower cost drug. As to Local 690, the 2AC cites the same two information-and-belief examples identified in the 1AC. (2AC ¶¶ 249-50) The 2AC offers nothing further to cure the deficiencies identified in my prior Opinion. Chief among those deficiencies is that the 2AC, like the 1AC, does not actually "allege that a drug switch was made by a pharmacy at all" but merely that a "medication 'was switched.'" (Op. 17) "[A] doctor, or the patient," as opposed to a pharmacist, I wrote, "could just have easily been the decision maker."[25] (*Id.*) The plaintiffs' sparse information-and-belief allegations—about their own members, remember—are not sufficient to establish a justiciable injury, let alone one

[25] It remains unexplained, for example, how a pharmacist could have made such a switch without a prescription (or really, why) from a physician in the first place.

caused by defendants' conduct. I therefore find that neither Local 690 nor DVHCC has standing to bring claims related to the diabetes drug scheme.

* * *

This 82-page, 369-paragraph 2AC contains many sweeping statements about the defendants' misuse of Hyalgan samples nationwide. It contains only an inadequate handful of factual allegations, however, about how that misconduct might have affected the members of Local 690 or DVHCC. And as to the diabetes drug scheme, there are essentially no connecting allegations. By squinting a bit, I can discern that DVHCC has alleged standing to bring claims on behalf of its New York and California members for prospective declaratory and injunctive relief, but only for conduct related to the free samples scheme, and only against Fidia. That said, the absence of factuality in the 2AC is acute, and that deficiency would persist even if Local 690 or DVHCC could somehow establish standing to pursue all of the claims asserted here.

IV. ANALYSIS: RULE 12(B)(6)

I turn to the motions insofar as they assert under Rule 12(b)(6) that the 2AC does not state a claim. Dismissal for failure to state a claim would be appropriate for many of the same reasons discussed above in relation to standing. And there are other grounds for dismissal as well.

A. Free Samples Scheme

1. Fidia

Because the standing analysis left only injunctive claims against Fidia, I first consider the viability of those remaining claims.[26] The 2AC, like the

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[26] I am mindful that the first step of the 12(b)(6) analysis is to "outline the elements a plaintiff must plead to state a claim for relief." *Bistrian*, 696 F.3d at 365. As explained in Part III.A., *supra*, however, the 2AC basically alleges that all defendants are responsible for the entirety of two different fraudulent schemes under five different states' laws. The papers do not clarify what conduct, if any, is particularly actionable under each state's law, or which defendant is particularly liable for that conduct. Like the parties, I therefore analyze the 12(b)(6) motions concurrently. I note, however, that the elements of the NYBGL, CUCL, CLRA, UTPCPL and MCPA are canvassed in Part

1AC, contains no sufficient allegation that any Fidia entity engaged in unlawful conduct at any time.[27] Reviewing the allegations of the 1AC, I found:

> These are conclusory allegations that lack any specific factual allegations of fraudulent or deceptive action by Fidia. Fidia licensed Hyalgan to Sanofi and allegedly knew about Sanofi's acts or advised Sanofi, in some unspecified way, regarding "strategy" relating to samples. There are no further allegations as to Fidia's role in any illicit action as it relates to Local 690. No specific factual examples are given. There are no allegations showing that any Local 690 beneficiary in Pennsylvania or New Jersey was affected. That Fidia regained control of Hyalgan distribution in 2011 is irrelevant: the alleged time period for the sample infractions is 2005-2009.

(Op. 20)

The 2AC does not meaningfully attempt to remedy any of these deficiencies; indeed, as to Fidia, the Second Amended Complaint is largely a cut-and-paste of the First. (ECF Nos. 104-3 ¶¶ 22, 72-77, 135, 137, 139, 264) (redline of the 1AC and 2AC, hereinafter "Redline")). True, there is a sprinkling of fresh allegations: *e.g.*, "Fidia committed to continuing the same marketing and sales practices" and "free samples practices started by Sanofi continued by Fidia." (2AC ¶¶ 81, 82) [28] These are too generic and conclusory to support a plausible inference of unlawful or fraudulent conduct.

II.C, and essentially all of them require some showing of harm or causation, which is one of the primary deficiencies here.

[27] I note that Fidia USA has reprised its argument that it cannot be held liable because it was incorporated only in 2011, after Sanofi's alleged wrongful conduct. Because the 2AC has failed to state a claim against any Fidia entity in any case, I need not reach this argument here. For the same reason, I also do not address its argument (joined by the Sanofi Defendants) that the free samples scheme claim is barred by prior release or res judicata.

[28] Nor am I persuaded by Exhibit A, attached to the 2AC, on which these allegations rely. The document is a letter, dated from August 2011, informing "Hyalgan prescribers that Fidia Italy, through Fidia USA, that Sanofi U.S. LLC will no longer distribute Hyalgan, that Fidia Italy, through Fidia USA, will distribute Hyalgan, and that "there will be no changes in how HYALGAN" will be supplied to prescribers. Plaintiffs take this as smoking-gun evidence of Fidia's participation in the free samples

The 2AC, in short, does not state facts that would give rise to a valid claim for relief under the NJCFA, UTPCPL, MCPA, CUCL, or CLRA.

2. Sanofi and Valentine

As to Sanofi and Valentine, I found that the 1AC failed to "explain the who, what, when, where, and how" of their alleged participation in the free samples scheme. (Op. 16) (citing *In re Suprema Specialties*, F.3d 217, 224, 276-77 (3d Cir. 2006)). Despite the opportunity to amend, that failure persists here.

Virtually all of the 2AC's key allegations are cribbed verbatim from the 1AC. For example, this is paragraph 175 of the 1AC:

> In particular, Local 690 and its beneficiaries paid for multiple injections of Hyalgan and Synvisc, based on Sanofi's and Genzyme's practices of providing free samples of Hyalgan and Synvisc who could be and were billed by doctors. The charges for such injections were at times as high [as] $1,460 for individual Hyalg[a]n prescriptions of which Local 690 paid 88.42 and the Local 690 member paid $247.11 . . . .

And these are paragraphs 247 and 248 of the 2AC (I have bolded the substantive addition):

> In particular, Local 690 and its beneficiaries, **and DVHCC and its members**, paid for multiple injections of Hyalgan for multiple plan beneficiaries, based on Sanofi's practices of providing free samples of Hyalgan could be and were billed by doctors. The charges for such injections were at times as high [as] $1,460 for individual Hyalgan prescriptions of which Local 690 paid $988.42 and the Local 690 member paid $247.11

Allegations like paragraph 247 and 248, I have already ruled, "lack the required specificity" to survive a motion to dismiss. And there are over a dozen

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scheme, but I do not read so much into it. This is a form letter addressed to customers of Hyalgan generally; its purpose to alert them to a change in the drug's distributor, and to allay any concern that contracts negotiated with Sanofi will not be honored or that the typical reimbursements will become unavailable. This letter does not establish in any way that Fidia engaged in unlawful conduct.

more pairs of 1AC/2AC allegations—averments explicitly discussed in my Opinion—just like it.[29] (*Compare* Opinion 15-19 (addressing the insufficiency of 1AC ¶¶ 75-76, 90-94, 97, 101, 103, 110-112, 123-24, 126, 202, 205), *with* Redline, ¶¶ 84, 86-87, 114, 119, 145-146, 149, 162, 164, 169-170, 182-82, 185, 252, 255 (allegations remain substantively unchanged)).

There are a couple differences between the allegations of the 1AC and 2AC, but they are immaterial. The allegations concerning Sanofi sales representatives' encouragement of billing for free samples are for some reason now pled with certainty rather than "upon information and belief." They are otherwise identical, however. (Op. 18-19; 2AC ¶¶ 169, 175-180) Then as now, the primary factual basis for believing Sanofi knew about and orchestrated the free sample scheme is that, by training sales reps in the *proper* use of samples in 2005, Sanofi was actually condoning the *improper* use of samples. It remains a *non sequitur*. (Op. 17-18 2AC ¶¶ 164-165) These amendments barely rise above the stylistic; they do not "plausibly suggest wrongdoing" under Rule 8(a) or satisfy the specificity required by Rule 9(b).

The 2AC's extensive citation to the Giddarie *qui tam* complaint and settlement is similarly unavailing. As discussed above, the Giddarie Settlement may support the inference that free Hyalgan samples were given out by someone to someone in New Jersey, California, Maryland, New York, and Pennsylvania at some point.[30] It says nothing about how the allegations connect to the beneficiaries or members of Local 690 or DVHCC. Plaintiffs have added a handful of new citations to the Giddarie complaint itself, but these,

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[29] Paragraphs 247 and 248, as it happens, are the only somewhat specific allegations addressing the Hyalgan prescriptions that DVHCC or Local 790 may have paid for. But these allegations still do not provide the where, when, and how necessary to state a claim.

[30] The full list of 20 states affected by the settlement are as follows: California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Massachusetts, Montana, Nevada, New Hampshire, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin. The District of Columbia is also alleged to have received settlement money from the Giddarie matter. (2AC ¶ 193)

too, are nothing more than generalized, sweeping allegations about Sanofi's practices. (*See, e.g.*, 2AC ¶¶ 101-106, 114-15) Incorporation by reference of an unrelated lawsuit does not excuse Local 690 or DVHCC from pleading the minimal factual support necessary to support their claims in this case.[31]

As to Valentine specifically, the 2AC, like the 1AC, alleges that Valentine delivered or supervised the delivery of samples of Hyalgan to doctors in California between 2006 and 2009, and was later censured for that conduct by the federal government. (2AC ¶¶ 47, 255-58; *see* Op. 20) But there is no allegation that connects his acts to any injury to the plaintiffs. For example, there is no pertinent factual allegation establishing that he delivered or supervised the delivery of a Hyalgan sample to a physician practice that treated a Local 690 or DVHCC member beneficiary, or that Local 690 or a DVHCC member actually paid for a Hyalgan sample that was mis-billed. (*Compare* 2AC ¶ 149a-d *with* 2AC Ex. C)[32]

In sum, insofar as DVHCC or Local 690 may be deemed to possess standing, the 2AC nevertheless fails to state a claim based on the free samples scheme against Fidia, Sanofi, or Valentine.

B. Diabetes Drug Scheme

No plaintiff, I have ruled, has standing to bring claims related to the diabetes drug scheme. Even if Local 690 or DVHCC had standing, however, I would dismiss the NJCFA, UTPCPL, MCPA, CUCL, and CLRA claims relating to the diabetes drug scheme against Accenture, Deloitte, and the Individual Sanofi Defendants.

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31 The rest of the 68-page Giddarie complaint contains many detailed factual averments individuals and events in Georgia, none of which are relevant to plaintiffs' claims here.

32 Because I have found that neither plaintiff has standing to pursue claims against Valentine, and that even if they did, their claims would be dismissed for failure to state a claim, I do not reach Valentine's fact-bound contention that he should be dismissed from this case for lack of personal jurisdiction.

My reasons are essentially those stated in my earlier Opinion, pp. 21-23, and in Part III.A.2, *supra*. That is so because the 2AC largely recapitulates the skimpy factual allegations of the 1AC (Redline ¶¶ 139, 144, 203-40, 245, 264), and what little is new is immaterial. Deloitte and Accenture, for example, are now alleged to have nationwide business operations, and their "techniques of secrecy" are said to be "identified" in the Giddarie complaint. (2AC ¶¶ 32, 35 265)[33] There is no mention of Accenture or Deloitte in the Giddarie complaint, however. The failure to specify the scope of these defendants' business activities was not one of the deficiencies of the 1AC. And the deficiencies that were identified in my prior Opinion have not been addressed by the 2AC.[34]

In the end, plaintiffs stand here today as they did a year ago. They claim that diabetes drugs were improperly switched at some cost to TPPs through illegal kickback agreements, although they aren't sure how and cannot state how they were harmed as a result. That is still not enough to state a claim under the NJCFA or UTPCPL. Nor do these allegations state a claim under MCPA, CUCL, or CLRA. As to all defendants, the 2AC must be dismissed for failure to state a claim related to the diabetes drug scheme.

C. Unjust Enrichment and Conspiracy

To the extent that any plaintiff has standing, the remaining tort claims must be dismissed as well. Under New Jersey law, to state a claim for

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33 There are no new allegations concerning the Individual Sanofi Defendants.

34 Those deficiencies included: (1) the lack of "essential details that would tie [Deloitte and Accenture] to the kickback scheme"; (2) that no specific pharmacy is alleged to have been involved in the kickback scheme or "that any such pharmacy served" Local 690 or DVHCC members' beneficiaries; (3) the absence of facts "suggesting that the scheme, however nefarious, had any effect" on plaintiffs or their members or beneficiaries; (4) that the examples of switching date from 2009 and 2011, "well before the 2012-13 time period of alleged kickback contacts"; (5) that a number of the allegations copied from the Ponte complaint are pleaded here with certainty, but in Ponte's complaint were pleaded on information and belief; and (6) that a related securities fraud complaint based on the whistleblower allegations of Ponte was itself dismissed for failure to state a claim in the Southern District of New York, *In re Sanofi Secs. Litig.*, 155 F. Supp. 3d 386 (S.D.N.Y. 2016). (Op. 21-23)

unjust enrichment, "a plaintiff must allege that (1) at plaintiff's expense (2) defendants received a benefit (3) under circumstances that would make it unjust for defendant to retain benefit without paying for it." *Synder v. Farnam Cos.*, 792 F. Supp. 2d 712, 724 (D.N.J. 2011); *see also VRG Corp. v. GKN Realty Corp.*, 641 A.2d 519, 526 (N.J. 1994). A civil conspiracy claim requires a properly pleaded unlawful act. *See G.D. v. Kenny*, 15 A.3d 300, 321 (N.J. 2011) (dismissing a civil conspiracy claim where the plaintiff could not "establish that defendants committed an unlawful act or a wrong against him that constitutes a tort entitled him to recovery.") For the reasons stated above, no plaintiff has pled any underlying unjust or unlawful action resulting in payment of money that it is entitled to recover. Because there is no unlawful act, it follows that the 2AC fails to state a claim for civil conspiracy.

V. CONCLUSION

For the reasons set forth above, the defendants' motions to dismiss for lack of subject matter jurisdiction and failure to state a claim are GRANTED. Plaintiffs, armed with specific instructions from the court, have already once been granted leave to remedy these basic pleading deficiencies, have enlisted the aid of a trade association which lacks standing, and have failed to remedy these defects. Because further amendment would be futile, this dismissal is with prejudice.

Dated: May 4, 2017

KEVIN MCNULTY
United States District Judge